# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Jeffrey W. Chambers Examiner: Brian E. Pellegrino

Serial No : 10/812,250 Group Art Unit: 3738 Docket No.: C364.105.101 Filed:

March 29, 2004

Due Date: September 29, 2009

Title: STENT POSITIONING SYSTEM AND METHOD

## REPLY BRIEF TO EXAMINER'S ANSWER

## Mail Stop Appeal Brief - Patents

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## Reply Brief Under 37 C.F.R. §41.41

This Reply Brief is responsive to the Examiner's Answer mailed June 16, 2009 and the corrective Examiner's Answer mailed July 29, 2009, and supports the Notice of Appeal filed on December 19, 2008 appealing from the final rejection dated September 19, 2009 of claims 28-45 of the above identified application. Twenty-nine claims remain for consideration.

The U.S. Patent and Trademark Office is hereby authorized to charge required fees to Deposit Account No. 50-0471 at any time during the pendency of this application.

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#### ARGUMENT

All arguments presented in Appellant's Brief are incorporated by reference herein. Further, Appellant responds to the Examiner's Answer as follows.

## I. The Methods Taught By Saltiel Require a Longitudinally Rigid Locator

Saltiel discloses methods employing a stent position device 10 incorporating an expandable member 20 to precisely position a stent relative to a vascular lumen. Saltiel, col. 1, l. 62 - col. 2, l. 9. The expandable member 20 includes an expandable member body 22 that is radially resilient and is longitudinally rigid. Saltiel, col. 3, ll. 35-38. This longitudinal rigidity is required by Saltiel so that as part of the corresponding methodologies taught by Saltiel, an overall length of the stent position device 10 does not change when the distal end 28 of the expandable member body 22 contacts an ostium. Saltiel, col. 3, ll. 38-41. Pointedly, the methods of Saltiel relies upon this longitudinal rigidity to affirmatively establish the predetermined distance or length L1 between the distal end 24 of the expandable member 20 relative to a proximal end of the manifold 14 in order to ensure precise, accurate positioning of the stent 100 relative to the distal end 24. Stated otherwise, with the methodologies of Saltiel, with the distal end 24 of the longitudinally rigid expandable member 20 in contact with the ostium, the known length L1 is established; the known length L2 between the stent 100 and a marker 60 (FIG. 4A) is also established and thus by locating the marker 60 at the manifold 14, the stent 110 is precisely located relative to the distal end 24 of the expandable member 20. If, however, the expandable member 20 were to longitudinally compress, the length L1 would deviate from the predetermined value, and so the stent 100 would no longer be precisely positioned relative to the distal end 24 upon locating the marker 60 at the manifold.

In light of the above, modifying the Saltiel to incorporate the alleged electrodes/leads 58 (or the hook 117) of Zikorus in place of the expandable member 20 would impermissibly render Saltiel inoperable and/or unfit for its intended purpose. The electrodes 58 and the hook 117 are clearly highly flexible, and do not exhibit longitudinal rigidity. Without this requisite

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longitudinal rigidity, the methods of Saltiel could no longer be performed as specified. Under these circumstances, an obviousness rejection cannot be maintained. MPEP 2143.01.

# II. Zikorus Does Not Teach a Method in Which Expandable Rods Determine Ostium Location Outside of the Vessel Itself

The Examiner's Answer appears to characterize Zikorus as teaching expandable rods and/or a hook to determine a vessel ostium. It is respectfully submitted that this is incorrect. Zikorus discloses various methods, and corresponding tools, employed to perform a ligation treatment in which an expandable RF electrode device 56 is placed at a treatment site of a vein and energized to shrink the vein wall. Zikorus at Para. 29. The treatment site of the vein can be near the sepheno-femoral junction (SJF) of the vein to be treated with another vessel, and the expandable RF electrode device 56 is initially located at the SJF and then pulled back to ligate an extensive section of the vein. Zikorus at Para. 26. According to the methods of Zikorus, the SJF can be located by ultrasound guidance (Para. 31), fiber optic light (Para. 33), or magnetically (Para. 38). Clearly, none of these three techniques are compatible with Saltiel, and do not teach the features of claim 28.

In addition to the above, Zikorus implies that a hook-shaped wire 87/117 can be used to "mechanically engage" the ostium of the SJF. Zikorus at Para. 44. The hook 87/117 is clearly not interchangeable with the longitudinally rigid expandable member 20 of Saltiel for the reasons described above. In addition, the method taught by Zikorus with respect to the hook 87/117 does not entail using the hook 87/117 to determine a location of the ostium based upon contact between the hook 87/117 and bodily structure apart from the vessel being treated as otherwise set forth in claim 28. Instead, because Zikorus specifies that the hook 87/117 is mechanically engaged with the ostium, it inherently must be in contact with the vessel to be treated itself, and not a bodily structure apart from the vessel. Also, nothing in Zikorus describes the hook 87/117 as being used to locate the vessel as an alternative to ultrasound, fiber optics, or magnetism; instead, the hook 87/117 merely serves to engage the vessel after it has been located. Finally, and as described in Appellant's Appeal Brief, the hook 87/117 is not radially expandable and

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thus if substituted for the expandable member 20 of Saltiel, would not teach each and every feature of claim 28.

Finally, Zikorus implies that a sensor 54 carried by one of the electrodes 58 (that in turn is carried by a flexible lead) can be used to "properly position" the catheter at the SJF. Zikorus, Para. 48. FIG. 4 of Zikorus illustrates a location of the sensor 54. The actual methods of Zikorus, however, do not teach use of the sensor to indicate a location of the ostium from a location outside of the vessel to be treated, in direct contrast to claim 28. More particularly, Zikorus states that the fiber optic device should be used with the sensor to position the catheter at the SJF. Zikorus, Para. 48. Impedance values provided by the sensor 54 are used to indicate whether the sensor 54 is in the blood stream or in contact with the vessel to be treated. Zikorus. Para. 43. Thus, the methods of Zikorus incorporating the sensor 54 require some other device to initially locate the ostium, and the sensor 54 itself is not in contact with a bodily structure apart from the vessel (to be treated) as set forth in claim 28. Inherently, because the sensor 54 is (and must be because it is carried by the RF electrode 58) in contact with the vessel wall, Zikorus cannot be reasonably viewed as teaching expanding a deployment site locator to a maximum outer dimension that is greater than the maximum dimension of the ostium, in direct contrast to claim 28. In other words, the maximum dimension of the ostium is inherently the same as the maximum dimension of the vessel; because the electrode 58/sensor 54 is expanded to a diameter that is equal to a diameter of the vessel, Zikorus cannot teach the method step of claim 28 in which an expansion greater than the maximum dimension of the ostium is achieved. Thus, modifying Saltiel in view of the sensor methods of Zikorus does not teach each and every feature of claim 28.

### III. Claims 43-45

In rejecting claims 43-45, the Examiner's Answer asserts that one of skill would have reasonably considered modifying the methods of Saltiel to provide "contact between an intermediate portion of the rod and the bodily structure" (claim 43), "radially deflecting the rod" (claim 44), or "radially displacing a free end of the rod" (claim 45). While the purported "rods"

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of Zikorus may or may not radially deflect, the Examiner's Answer fails to address the fact that the proposed modification of the methods of Saltiel would impermissibly render Saltiel unfit for its intended purpose and/or change its principle of operation. As described above, Saltiel is premised upon use of the longitudinally rigid expandable member 20. No radial displacement if the member 20 can occur in response to contact with structures of the ostium. Thus, modifying Saltiel in accordance with any of claims 43-45 is adverse to the requirements of Saltiel, such that an obviousness rejection cannot stand.

#### CONCLUSION

Any inquiry regarding this Reply Brief should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

Jeffrey W. Chambers,

By his attorneys

Date: Date:

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